## UNITED STATES DISTRICT COURT SOUTHERN DISTRICT OF NEW YORK

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ASSOCIATION FOR MOLECULAR PATHOLOGY;
AMERICAN COLLEGE OF MEDICAL GENETICS;
AMERICAN SOCIETY FOR CLINICAL PATHOLOGY;
COLLEGE OF AMERICAN PATHOLOGISTS;
HAIG KAZAZIAN, MD; ARUPA GANGULY, PhD;
WENDY CHUNG, MD, PhD; HARRY OSTRER, MD;
DAVID LEDBETTER, PhD; STEPHEN WARREN, PhD;
ELLEN MATLOFF, M.S.; ELSA REICH, M.S.;
BREAST CANCER ACTION; BOSTON WOMEN'S
HEALTH BOOK COLLECTIVE; LISBETH CERIANI;
RUNI LIMARY; GENAE GIRARD; PATRICE
FORTUNE: VICKY THOMASON; KATHLEEN RAKER,

09 Civ. 4515 (RWS)

ECF Case

## Plaintiffs,

V.

DECLARATION OF GENAE GIRARD

UNITED STATES PATENT AND TRADEMARK OFFICE; MYRIAD GENETICS; LORRIS BETZ, ROGER BOYER, JACK BRITTAIN, ARNOLD B. COMBE, RAYMOND GESTELAND, JAMES U. JENSEN, JOHN KENDALL MORRIS, THOMAS PARKS, DAVID W. PERSHING, and MICHAEL K. YOUNG, in their official capacity as Directors of the University of Utah Research Foundation,

## Defendants.

1. My name is Genae Girard. I am a Plaintiff in the above-captioned case.

- 2. I am a 39-year-old woman living in Texas.
- 3. In July 2006, when I was 36 years old, I was diagnosed with breast cancer in my left breast. After consulting with a genetic counselor and other doctors about the best course of treatment, I decided to have genetic testing performed to help assess my hereditary risk of cancer and how aggressive my treatment should be. Because a BRCA mutation would indicate that I

was at a high future risk of another occurrence of breast cancer and of ovarian cancer, I knew that the test results could be crucial in making my medical decisions.

- 4. I was tested in December 2006 and was informed that I was positive for a deleterious mutation on my BRCA2 gene. My doctors told me that the positive result should be a major factor in deciding whether to get prophylactic bilateral breast surgery and ovarian surgery, particularly because it is difficult to screen for ovarian cancer.
- 5. I asked if I could get the test results verified through another lab. I know that no medical test can be perfectly accurate in every situation and that laboratories and doctors sometimes make mistakes. I also know that laboratories perform different types of tests, and that it can be useful to have your samples tested using more than one method. Once I was diagnosed, I promised myself to get second or third opinions on test results and proposed courses of treatment.
- 6. However, I was told that, for this important test which raised the question of prophylactic, surgical removal of both my breasts and ovaries, I could not have another laboratory perform the testing. No laboratory other than Myriad Genetics could perform full sequencing of the BRCA genes. I learned that Myriad was the only lab that could do this testing because it controlled patent rights over the BRCA1 and BRCA2 genes.
- 7. I faced life-altering decisions without being able to verify my test results.

  Bilateral breast and ovarian surgeries reduce one's risk of cancer, but they are also major procedures that require long periods of recovery and the premature and permanent loss of hormones, with possibly serious side effects. Oophorectomy also ends the future possibility of having children.

- 8. My genes also have implications for my family members. Because I tested positive for a particular mutation, genetic testing guidelines provide that my family members who want to pursue testing should receive a type of test that looks specifically for the mutation that has been identified on my BRCA2 gene. I would not want my family's testing to be based on my single result either.
- 9. Two and a half years have now passed, and I still live with the uncertainty and frustration that comes from not being able to confirm my BRCA2 positive test result.
- 10. If I learned that Myriad's patents on the BRCA1 and BRCA2 genes were invalidated, I would take action right away. I would pursue and order BRCA genetic testing through another laboratory. Without the patents, geneticists and laboratory professionals other than Myriad would be able to offer BRCA full sequencing. I would be able to confirm that my BRCA2 gene does have the identified mutation and make life decisions accordingly. This is not just speculation on my part. I understand that some of the other plaintiffs in this case, including Dr. Chung and Dr. Ostrer, would offer BRCA genetic testing to me if the patents were no longer a barrier. I would immediately seek testing through their laboratories if the patents were no longer in effect.
- 11. The reason I have not been able to obtain a second BRCA genetic test to date is that the gene patents prevent any other laboratory in the United States from performing BRCA full sequencing for patients. If the patents were invalidated, I could finally get another test done and more fully understand my genes and my hereditary risk for cancer.

I declare, pursuant to 28 U.S.C. § 1746, un	der penalty of perjury under the laws of the
United States, that the foregoing is true and correct	et to the best of my knowledge and belief
Executed on August $\frac{9}{2}$ , 2009	Lun M Led
•	GENAE GIRARD